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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/084,952 | 03/01/2002 | Stanley F. Harrison JR. | 4053-001 | 8292 |

7590 03/14/2005

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| EXAMINER | |
|---|---|
| MARX, IRENE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/084,952 | HARRISON, STANLEY F. | |
| | Examiner | Art Unit | |
| | Irene Marx | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *16 February 2005 and 27 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The amendment filed 2/16/05 and arguments filed 1/27/05 are acknowledged. Claims 8-9 are being considered on the merits.

Applicant's request for an RCE is noted. However, the request is premature since the case is not after final. It can properly be filed in response to this Office action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the treatment of excessive blood lipid levels in humans with "exclusively" the recited composition. The invention as claimed reads on the treatment of obesity, amount other conditions.

Insertion of the limitation "exclusively" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the use of the composition indicated "exclusively" to treat excessive blood lipids. The methods exemplified are directed to the use of "medication according to this invention". This is not sufficient support for the new genus of using "exclusively" the recited composition in the absence of food or drink or of other medications. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact.

To complicate matters further, Thus, the insertion of "exclusively" is considered to be the insertion of new matter for the above reasons.

Applicant did not address this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 is vague, indefinite and confusing in that it is unclear what is intended by "excessive" in this context. It is not apparent that high levels of HDL are undesirable, for example. There is no clear indication of the amount or lipids intended to be "treated" or the effect to be achieved.

Claim 8 is vague, indefinite and confusing in that it is unclear what is intended by "exclusively" in the present context, even when interpreting the claim in light of the specification. See also the new matter rejection supra. It is uncertain how this "exclusivity" is to be determined, particularly since the condition to be treated is not particularly defined. Treatments of various conditions related to excess blood lipid levels are effected with different processes, including mild to drastic adjustments to the diet, in view of the health risks associated with excess lipid levels in blood are involved in obesity, heart disease, diabetes and other metabolic diseases. In addition, it is noted that prescription drugs often become "non-prescription, over the counter" drugs upon expiration of a patent, for example. It is unclear how this change would affect the claimed invention. Moreover, it is uncertain whether "exclusively" does or does not preclude the treatment by other means, such as diet and non-traditional medications or preclude a subject from taking prescription medications for related or unrelated conditions.

Therefore, the metes and bounds of the claims are not delineated with sufficient clarity.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The definition of the term "excessive" in the references provided clearly demonstrate that this term requires evaluation in each individual case depending on risk factors, etc. Therefore, the term is ambiguous and open to interpretation in it present context.

Applicant does not address the rejection regarding "exclusively", which term is present in the claims submitted on 2/16/05.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 9 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Schlachter *et al.* taken with Hoie, Burr *et al.,* Cochran *et al.*, and Kirschman *et al.*

Schlachter *et al.* teaches the administration of a food supplement composition comprising fish oil containing DHA and EPA, niacin and soy lecithin as a dietary supplement orally and daily. Inasmuch as most males have excessive blood lipids in need of treatment, and that each of the ingredients in the composition is well known in the art of be suitable for the required purpose, it is submitted that the reference teaches the claimed method of treatment, even though there are further ingredients in the composition. Regarding the use of the ingredients claimed in the treatment of excessive blood lipids, see, e.g., Hoie col. 4, lines 20 et seq. Moreover, Hoie teach the administration of a soybean preparation in combination with fish oil concentrates and nicotinic acid derivatives. (See, e.g., col. 22, lines 47 et seq.).

The references differ from the claimed invention in that the specific formulations encompassed are not taught and that further material is included in the preparation. It is noted in this regard that the gel capsules to be administered as per the instant invention also comprise unknown and/or undefined materials. In addition, the claim designated preparations are

commercially available preparations as admitted in the as filed specification. See, e.g., page 4, last paragraph and page 5. Thus, one of ordinary skill in the art would have reasonably expected at the time the claimed invention was made that these compositions were taken orally routinely in various combinations, including the combination as claimed.

Burr *et al.* is cited to demonstrate that fish oil was recognized in the art to treat excessive blood lipid levels in humans at the time of invention (See, e.g., page 186). Cochran *et al.* is cited to demonstrate that inositol hexanicotinate was recognized to treat excessive blood lipid levels in humans at the time of invention (See, e.g., col. 10, lines 15-55). In addition, Kirschman *et al.* disclose that lecithin is required to break down cholesterol and fats in the blood, which treats excessive blood lipid levels (See, e.g., page 122). It is noted that the use of niacin is also recommended.

The optimization of conditions identified as result-effective variables cited in the references, such as dosage and form of administration would have been prima facie obvious to a person having ordinary skill in the art, since the compositions to be administered are admitted in the specification to be old and well known in the art.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of providing a food supplement of Schlachter *et al.* by providing at least the specific ingredients disclosed by Hoie, Burr *et al.*, Cochran *et al.*, and Kirschman *et al.* to be most likely to effectively treat excessive blood lipids and provide the ingredients in the formulations admitted by applicants to be old and well known in the art for the expected benefit of successfully minimizing the risk of cardiovascular disease by decreasing lipid levels in blood of compounds such as total cholesterol, LDL and triglycerides while maintaining a high HDL level, as recommended by Cochran *et al.* by using niacin and derivatives.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant(s) argue(s) that there is no suggestion to combine references. However, motivation can come not only from direct teaching of the prior art, but also the nature of the problem to be solved and/or the knowledge of persons of ordinary skill in the art, Ruiz v. A.B. Chance Co. 357 F.3d 1270, 69 USPQ2d 1686 (2004). The cited references are in the same field of endeavor and seek to solve the same problems of providing proper nutrients as the instant application and claims, and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966). Further, the examiner recognizes that references cannot be arbitrarily combined that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references, *In re* Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. One test for combining references is what the combination of disclosures taken as a whole would suggest to one versed in the art, rather than by their specific disclosures, *In re* Bozek, 163 USPQ 545 (CCPA 1969). In this case, the prior art combination of inositol hexanicotinate, eicosapentaenoic acid, docosahexaenoic acid, phosphatidyl choline, phosphatidyl ethanolamine, and phosphatidyl used for their known art specific properties, in different combinations and in the presence of other ingredients that do not affect their effectiveness as nutritional preparations is considered to be obvious in the absence of evidence to the contrary.

Moreover, "[[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co., Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The examiner relies on Schlater *et al.* for the disclosure of the administration of a food supplement composition comprising fish oil containing DHA and EPA, niacin and soy lecithin as a dietary supplement orally and daily to subject more than likely to have "excessive blood lipids" The deficiencies argued by applicants in the secondary references fail to recognize that all of the secondary are relied on for teachings of the treatment of similar conditions. For example, Hoie teach the administration of a soybean preparation in combination with fish oil concentrates and

nicotinic acid derivatives. (See, e.g., col. 22, lines 47 et seq.). The secondary references are relied on only for their disclosure of knowledge in the art of the effectiveness of the claimed methods. In this regard, Burr *et al.* is cited to demonstrate that fish oil was recognized in the art to treat excessive blood lipid levels in humans at the time of invention (See, e.g., page 186). Cochran *et al.* is cited to demonstrate that inositol hexanicotinate was recognized to treat excessive blood lipid levels in humans at the time of invention (See, e.g., col. 10, lines 15-55). In addition, Kirschman *et al.* disclose that lecithin is required to break down cholesterol and fats in the blood, which treats excessive blood lipid levels (See, e.g., page 122). It is noted that the use of niacin is also recommended.

Applicant has not demonstrated unexpected results with the touted method.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651